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10/509,539	09/28/2004	Shigeyoshi Fujiwara	26170/168578	7836
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ANDREWS KURTH LLP 1350 I STREET, N.W. SUITE 1100 WASHINGTON, DC 20005			EXAMINER BARHAM, BETHANY P	
			ART UNIT	PAPER NUMBER
			1615	
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

### Office Action Summary

**Application No.**

10/509,539

**Applicant(s)**

FUJIWARA ET AL.

**Examiner**

BETHANY BARHAM

**Art Unit**

1615

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 15 May 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 2, 4, 5, 15-17 and 19-32 is/are pending in the application.
- 4a) Of the above claim(s) 25-32 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) 2, 4, 5 and 15-24 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/S508)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Summary***

Receipt of Applicant's Response filed on 5/19/09 is acknowledged. Claims 2, 4-5, 15-17 and 19-32 are pending.

### **Response to Restriction**

Applicant argues that there was no previous restriction requirement in the case to require Applicant to elect claims drawn to separate classes. However, the Examiner respectfully points out that the claims were elected by original presentation (See 37 CFR 1.142(b) and MPEP § 821.03.), but the product by process claims (claims 19-24) were incorrectly withdrawn and herein reinstated and are rejected over the prior art references of record.

Previously submitted claims 25-32 remain withdrawn since they are directed to method of making claims which is an invention that is independent or distinct from the invention originally claimed for the following reasons: Original claims were drawn to a powder, a product containing the powder and various uses of the powder on skin.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 25-32 withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03. Claims 2, 4-5, 15-17 and 19-24 are examined and rejected.

**MAINTAINED REJECTIONS**

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 2, 4-5, 15-17 and 19-24 are rejected under 35 U.S.C. 102(b) as being anticipated by JP 05058624 A.

- '624 teaches the preparation of barium sulfate powder wherein the process for producing the powder starts with a) a barium ion such as barium compounds  $\text{Ba}(\text{OH})_2$ ,  $\text{BaCl}_2$ , etc ; b) in the presence of one or more metallic ion such as sodium ions  $\text{Na}_2\text{SO}_4$ ,  $\text{NaHSO}_4$ , etc. Note the sodium ions contain sulfate ions (see the enclosed abstract).
- '624 teaches that the powder has a size of 4-20 microns (abstract).
- '624 teaches that the pigment is for use in cosmetics (abstract). It is the examiners opinion that the powder provides a barrier to the skin and prevents a roughening of the skin since it is the same powder and is described as being used in cosmetics.
- '624 is silent with respect to zeta potential however as a matter of claim interpretation the Examiner respectfully points out that the zeta potential of a compound is measured by putting that compound in solution (instant claims are drawn to a powder):

kinetic or zeta potential from the equation

$$\zeta = \frac{4\pi NKE}{DP}$$

where  $N$  is the viscosity,  $D$  the dielectric constant,  $P$  the measured pressure,  $E$  the measured potential, and  $K$  the specific conductance of the solution in the diaphragm. The values of  $N$  and  $D$  were taken from standard tables.

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- First, Reyerson et al (1946) teaches barium sulfate particles from 1-5 microns made from a mixture of barium chloride and potassium sulfate (pg. 323) and teaches that the zeta potential of the barium sulfate changed with aging, solvent and additives (pg. 324-326); in water it was a negative zeta potential and with 'indifferent electrolytes' (pg. 325), while in 50% ethanol the zeta potential was positive and lithium sulfates were added to increase the negative potential (pg. 326). Thus, according to Reyerson the electrolytes, solvent and aging all affect the zeta potential and can change its value from negative to positive.
- Second, "Zeta potential" teaches that zeta potential is a physical property of any particle in suspension (pg. 1, intro.) and that several factors affect zeta potential (1)pH, (2) conductivity and (3) concentration (pg. 3-4). According to the reference "a zeta potential value on its own without defining the solution condition is a virtually meaningless number. Imagine a particle in suspension with a negative zeta potential. If more alkali is added...then the particles tend to acquire more negative charge. If acid is added...the a point will be reached where the charge will be neutralized...further addition of acid will cause a...positive charge" (pg. 3 (col. 3, bottom)-pg. 4 (col. 1, top)).

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- Thus the Examiner respectfully points out that the zeta potential of a compound is measured by putting that compound in solution and this claim is drawn to a powder not a solution, thus the Examiner is interpreting “a zeta potential value on its own without defining the solution condition is a virtually meaningless number”.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 2, 4-5, 15 and 19-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bloom et al (*J. Chem. Soc. A*, 1971, 833 – 836) in view of CA 2,374,539 ('539).

- Bloom et al teaches barium sulfate being doped with alkali metal salts, such as sodium (abstract, pg. 834, column 1, top).
- 'Bloom et al is silent with respect to zeta potential however as a matter of claim interpretation the Examiner respectfully points out that the zeta potential of a compound is measured by putting that compound in solution (instant claims are drawn to a powder):

kinetic or zeta potential from the equation

$$\zeta = \frac{4\pi NKE}{DP}$$

where  $N$  is the viscosity,  $D$  the dielectric constant,  $P$  the measured pressure,  $E$  the measured potential, and  $K$  the specific conductance of the solution in the diaphragm. The values of  $N$  and  $D$  were taken from standard tables.

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- The Examiner respectfully points out that Applicant's claims are not drawn to a solution but a powder and thus the zeta potential measurement is not appropriate (see cited prior art below).
- First, Reyerson et al (1946) teaches barium sulfate particles from 1-5 microns made from a mixture of barium chloride and potassium sulfate (pg. 323) and teaches that the zeta potential of the barium sulfate changed with aging, solvent and additives (pg. 324-326); in water it was a negative zeta potential and with 'indifferent electrolytes' (pg. 325), while in 50% ethanol the zeta potential was positive and lithium sulfates were added to increase the negative potential (pg. 326). Thus, according to Reyerson the electrolytes, solvent and aging all affect the zeta potential and can change its value from negative to positive.
- Second, "Zeta potential" teaches that zeta potential is a physical property of any particle in suspension (pg. 1, intro.) and that several factors affect zeta potential (1)pH, (2) conductivity and (3) concentration (pg. 3-4). According to the reference "a zeta potential value on its own without defining the solution condition is a virtually meaningless number. Imagine a particle in suspension with a negative zeta potential. If more alkali is added...then the particles tend to acquire more negative charge. If acid is added...the a point will be reached where the

charge will be neutralized...further addition of acid will cause a...positive charge"  
(pg. 3 (col. 3, bottom)-pg. 4 (col. 1, top)).

- Bloom et al does not teach a size in microns or aspect ratio but teaches they were 0.5-3 Mrad.
- '539 teaches a doped barium sulfate of 0.0005 to 5 microns in diameter in the amount of 1-30% by weight (claims 1, 5-7 and pg. 12, line 43-pg. 13, line 7).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to size the doped Barium Sulfate particles of Bloom et al to be similar to that of '539. The skilled artisan would know how to combine the Bloom et al known product and '539 known technique to yield predictable results. It is within the purview of the skilled artisan to use the '539 known technique of producing barium sulfate particles of a specific size (0.0005-5 microns) in combination with the Bloom et al known product (ie. doped barium sulfate powder) to yield predictable results. One of ordinary skill in the art would know how to optimize the ranges of Bloom et al in view of '539, as the MPEP 2144.05 states "Where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation."

Claims 2, 4-5, 15-17 and 19-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over JP 05058624 A in view of US 6,632,276 ('276).

- '624 is taught above and teaches doped barium sulfate powder with a size of 4-20 microns for use in cosmetics (abstract). It is the examiners opinion that the powder provides a barrier to the skin and prevents a roughening of the skin since



it is the same powder and is described as being used in cosmetics (as instant claimed in claim 9-11 and 15-17).

- '624 does not teach aspect ratio of the particles.
- '276 teaches the preparation of barium sulfate with a size of less than 200 microns, preferably less than 50 microns, with an aspect ratio of more than 3, and in particular more than 5 (col. 2, lines 21-35).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to measure the aspect ratio of a particle of '624 doped barium sulfate of substantially the same size as taught by technique of '276. The skilled artisan would know how to combine the '624 known product and '276 known technique to yield predictable results. It is within the purview of the skilled artisan to use the '276 known technique of producing barium sulfate particles of the same size with an aspect ratio of more than 3, particularly more than 5 ('276 col. 2, lines 21-35) in combination with the '624 known product (ie. doped barium sulfate powder) to yield predictable results.

### ***Response to Arguments***

Applicant's arguments with respect to claims 2, 4-5, 15-17 and 19-24 have been considered but are not persuasive. Applicant states that the composition of Bloom et al although formed via a different process is 'doped' but that the composition of '624 is not 'doped' (response pg. 11, last paragraph and response pg. 8-pg. 9). Applicant argues that the Examiner cannot "arbitrarily assert...that the claimed doped barium sulfate includes the barium sulfate of JP 624." The Examiner respectfully points out that this assertion was based on the fact that the same mixture of components in Bloom et al as

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in '624 yielded doped barium sulfate, namely a mixture of barium chloride (A) and sodium sulfate (B+C) produced barium sulfate that was 'doped' with sodium ions (Bloom et al pg. 34, col. 1 and Fig. 1 and '624 abstract). Applicant argues that the instant spec teaches that doped barium sulfate cannot be formed from a one step process (response pg. 8), however this is contrary to the prior art teaching of Bloom et al (above) and the response rendered by Applicant (response pg. 11, last paragraph). Thus, it would appear that the '624 reaction of barium chloride and sodium sulfate would also predictably produce barium sulfate that was 'doped' with sodium ions as confirmed by Bloom et al and Applicant (response pg. 11, last paragraph).

Further, Applicant cannot argue method claims against the instant composition or use claims of 2, 4-5, 15-17 and 19-24. The instant claims are drawn to a product, use and product by process and the MPEP 2113 states:

"[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985) (citations omitted). "The Patent Office bears a lesser burden of proof in making out a case of prima facie obviousness for product-by-process claims because of their peculiar nature" than when a product is claimed in the conventional fashion. In re Fessmann, 489 F.2d 742, 744, 180 USPQ 324, 326 (CCPA 1974). Once the examiner provides a rationale tending to show that the claimed product appears to be the same or similar to that of the prior art, although produced by a different process, the burden shifts to applicant to come forward with evidence establishing an unobvious difference between the claimed product and the prior art product. In re Marosi, 710 F.2d 798, 802, 218 USPQ 289, 292 (Fed. Cir. 1983).

Thus the burden shifts to Applicant to show that the prior art does not teach the instant claimed powder, product, use of product and that the product by process of claims 19-24 produces a materially different product than the prior art.

Applicant also argue that the rejection of '624, '624 in view of '276 and Bloom et al in view of '539 is improper, because the art ('624 or Bloom et al in view of '539) is silent with respect to the aspect ratio or negative zeta potential.

**Aspect Ratio:**

Firstly, the Examiner respectfully points out that instant spec Tables 1-3 only teach aspect ratio values of 3-250 for the products barium sulfate alone and doped barium sulfate (Examples 1-12 do not teach aspect ratio values and Ex.13-16 teach a value of "-", while Ex.17-21 teach 3-250 regardless of doping) and as such it would appear that doped or undoped barium sulfate yields an aspect ratio value of at least 3 and up to 250 (see Table 3 Ex. 17-21) and the prior art anticipates or is obvious over the instant claims. Further, specifically with respect to the combination of '624 known product and '276 known technique to yield predictable results ('276 does teach a known technique of producing barium sulfate particles of the same size with an aspect ratio of more than 3, particularly more than 5 ('276 col. 2, lines 21-35), while '624 teaches the product is known (ie. doped barium sulfate powder))) and as such this rejection of record is proper and hereby maintained.

**Negative zeta potential:**

As such the cited art (Reyerson et al and "Zeta potential) teach that zeta potential depends on the suspension that the particle is in and the pH, conductivity and concentration of the particle and electrolytes and the instant claims are drawn only to a powder, not a suspension and as such zeta potential is 'virtually meaningless'

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(according to "Zeta potential"). Absent a showing of unexpected results by Applicant that the particles have different aspect ratios or zeta potential values, the rejection stands. The Office is not equipped to test the instant claims against the prior art, and as such the burden falls to Applicant to produce a side-by-side comparison, measurement, statistical data, showing that the particles formed result in divergent aspect ratios from the instant claimed particles. Applicant appears to be claiming a physical property of the compound of the same composition and size as taught in the art. MPEP 716.02 states "Evidence of unobvious or unexpected advantageous properties, such as superiority in a property the claimed compound shares with the prior art, can rebut *prima facie* obviousness. " Evidence that a compound is unexpectedly superior in one of a spectrum of common properties . . . can be enough to rebut a *prima facie* case of obviousness." No set number of examples of superiority is required. *In re Chupp*, 816 F.2d 643, 646, 2 USPQ2d 1437, 1439 (Fed. Cir. 1987)". The burden is on Applicant to provide such evidence and arguments do not take the place of such evidence.

#### **CITED AS INTEREST**

Reyerson et al (1946) teaches barium sulfate particles from 1-5 microns made from a mixture of barium chloride and potassium sulfate (pg. 323) and teaches that the zeta potential of the barium sulfate changed with aging, solvent and additives (pg. 324-326).

"Zeta potential" teaches that several factors affect zeta potential (1)pH, (2) conductivity and (3) concentration (pg. 3-4) and that "a zeta potential value on its own without defining the solution condition is a virtually meaningless number."

### **Correspondence**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bethany Barham whose telephone number is (571)272-6175. The examiner can normally be reached on M-F, 8:30 am to 5 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on 571-272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Bethany Barham  
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/Tracy Vivlemore/  
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